File: www.cdc.gov/nip/visi/meeting-archives/VISIannounceConfCall-23Feb2000.pdf

From: Weniger, Bruce
Sent: 22 February, 2000 20:54

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Cc: Broom, William; Cordero, Jose; Destefano, Frank; Egan, William (FDA CBER); Haber, Penina; Hibbs, Beth; Hurley, Hope (AAP); Kramarz, Piotr; Linkins, Rob; Livengood, John; Mootrey, Gina; Myers, Martin; Nichols, Bill; Orenstein, Walt; Pool, Vitali; Rodewald, Lance; Schwartz, Benjamin; Sepe, Stephen; Snyder, Bob; Vernon, Thomas (Merck)
Subject: VISI conference call; progress update

Dear VISI work group member,

After a too-long hiatus, we are pleased now to schedule a conference call, and to brief you on the progress to date and status of the various components of the Vaccine Identification Standards Initiative (VISI).

As increasing attention is paid to monitoring the safety of vaccines, the goals of VISI to improve the accuracy and convenience of transferring identifying information from vaccine vial into medical record are receiving much attention. For example, VISI was discussed prominently at the recent international symposium on combination vaccines in Bethesda, MD.

We need to poll your preferences for the timing of the next VISI working group conference call. We have arbitrarily selected three possible timeslots. We request you reply to Bindi Patel <bpatel@cdc.gov> indicating each as "preferred", "OK", or "unavailable":

Tues	14 March:	10:00am	- 11:00+ am EST
Wed	15 March:	4:00pm	- 5:00+ pm EST
Fri	17 March:	12:00noon	- 1:00+ pm EST

We will select the timeslot that maximizes participation, recognizing that it is virtually impossible to find any one time that would satisfy the

busy schedules of the many people on the VISI working group. If you are unable to participate, please try to identify (an)other person(s) to provide your and your organization's input.

Below please find the progress report. Please note that VISI is not yet prepared for the public dissemination and comment phase of the initiative.

THEREFORE, PLEASE DO NOT CIRCULATE OUTSIDE YOUR ORGANIZATION THE "UNLISTED" WEB ADDRESSES AND OTHER VISI COMPONENTS BELOW. Please ensure your organization's addressees for internal circulation are aware of this request, and channel through you their feedback about VISI.

Thank you.

Bruce

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---------- VISI UPDATE ----------

1. FORMAL NARRATIVE TEXT FOR VISI PROMULGATION
2. NATIONAL DRUG CODE (NDC) VACCINE DATABASE
3. VACCINE FACTS INFORMATION SIDEBAR
4. BARCODING OF SECONDARY PACKAGING
5. BARCODED PEEL-OFF STICKERS ON VIALS
6. UNIFORM VACCINE ADMINISTRATION RECORD (UVAR) FORM
7. UNIFORM VACCINE AND MANUFACTURER ABBREVIATIONS

1. FORMAL NARRATIVE TEXT FOR VISI PROMULGATION

1.1 This overarching narrative text will contain the background, rationale, methodology, principles, and detail of all the VISI components, references, and background tables.

1.2 TO BE DONE: (1) Such a document remains to be drafted for working group review, dissemination for public comment, receipt, review and tabulation of such comment, formatting, editing, and final publication. (2) Personnel and/or contracting resources need to be identified to complete various editorial, database, webmastering, graphics, and related tasks,

and to shephered VISI through public comment and final publication stages.

2. NATIONAL DRUG CODE (NDC) VACCINE DATABASE

2.1 VISI proposes to use the National Drug Code as the unique number to identify vaccines for barcoding purposes. The NDC is a 10-digit number that appears on every pharmaceutical vial ("1° packaging") and box ("2° packaging") distributed in the United States. See:
http://www.uc-council.org/focus_by_industry/fi_primary_information_request.html
One vaccine type from a particular manufacturer may have multiple NDCs because its final 1-or-2-digit string indicates its packaging type (e.g., single-dose vial, multi-dose vial, 10-pack of single-dose vials, prefilled syringes, etc.)

2.2 The main obstacle to the use of the NDC within the scope of the VISI is that there has been no authoritative, universally-accessible, free-of-charge, easy-to-use, up-to-date, user-friendly database linking NDC numbers to the corresponding manufacturer, product identity and other information (and vice versa). Such a database would be helpful for developers of software programs for medical practice record-keeping and immunization registries, which require "lookup tables" which convert NDC numbers received from bar code scanners into their plain-English identities.

2.3 To meet this need, VISI has produced a pilot NDC Vaccine Database (credit and thanks go to Bindi Patel and Suzy Feikema for this effort). Athough it remains to be determined which organizational unit or agency would assume long-term responsibility for maintenance of this resource, CDC/NIP's Vaccine Safety and Development Branch (VSDB) is currently serving this role.

2.4 The pilot VISI NDC Vaccine Database is located at <http://www.cdc.gov/nip/visi/ndcsearch/ndcsearch.htm> [Note: the latest format and database will not be uploaded until the evening of 23-Feb-2000.] Eventually the current source database will be downloadable via the web in its native format (MS Access '97).

2.5 These engine-search summary and web-page formats are still being fine-tuned. We are sure there exist errors of omission and commission in the data. Manufacturers are urged to report any product-specific errors or omission at any time to Bindi <bpatel@cdc.gov>.

2.6 TO BE DONE: (1) Database needs corrections and additions by manufacturers. (2) Database needs reformatting of search summaries and output pages. (3) This project needs designation of unit/agency to assume long-term maintenance and public availability of this and more comprehensive related vaccine databases, and their potential conversion to more sophisticated database systems for web-based access.

3. VACCINE FACTS INFORMATION SIDEBAR

3.1 VISI recognizes that any change to be effected in the packaging and labelling of every vaccine product will require regulatory interaction between the manufacturer and the FDA. With that given, VISI proposes a section of the secondary packaging (cardboard box) of vaccines be used for a "sidebar" to contain "VACCINE FACTS". This would be analogous to the "NUTRITION FACTS" sidebar mandated by FDA for all retail food packages in the United States. If necessary, the Vaccine Facts sidebar could run over an edge to occupy adjacent faces of typical 6-sided packaging.

3.2 The information to be included in a standardized layout and format would be (1) full generic vaccine name, (2) brandname, (3) vaccine type code (abbreviation), (4) manufacturer code (abbreviation), (5) NDC number, (6) expiration date, (7) lot number, (8) volume and packaging, (9) number of doses, (10) refrigeration and handling requirements and warnings, (11) any preservatives or allergenic ingredients, (12) dosing volume and route, (13) full name of distributor and contact telephone number, and (14) full name of manufacturer. Here is an early prototype Vaccine Facts sidebar that now needs updating of the vaccine abbreviation used and manufacturer name: <http://www.cdc.gov/nip/visi/prototypes/draftprototypevaccinefacts.htm>.

3.3 TO BE DONE: (1) Working group needs to decide whether space should be saved within the Vaccine Facts sidebar for "online printing" at the time of filling of the lot number and expiration date, or whether such printing should be located elsewhere on the box. (2) The existing sample sidebar must be updated. (3) Additional samples illustrating different types of information included in the sidebar need to be prepared for complicated vaccines from other major vaccine manufacturers in the U.S. (4) The draft narrative specifying the format for the Vaccine Facts labelling must be written to mimic the FDA language in 21 CFR 101.9(d) which sets forth the standards for the Nutrition Facts sidebars. See: <http://vm.cfsan.fda.gov/~dms/flg-5-1.html>.

4. BARCODING OF SECONDARY PACKAGING

4.1 VISI will propose that all secondary vaccine packaging (cardboard box) include a full-size barcode (x-dimension >=# mils) embedding (1) the NDC, (2) the expiration date, and (3) the lot number, according to UCC-EAN-128 standards for small pharmaceutical packages: <http://www.uc-council.org/focus_by_industry/fi_data_element_requirements.html>. This barcode should be capable of being read by the least expensive scanning hardware that a physician's office might already use.

4.2 TO BE DONE: (1) A minimum resolution must be proposed for the x-dimension of the barcode which determining its "laser legibility", based on trading off size and compatibility with existing, low-priced scanners. (2) The VISI narrative language specifying these barcode

standards remains to be drafted.

5. BARCODED PEEL-OFF STICKERS ON VIALS

5.1 VISI will propose that 2 (duplicate) or 3 (triplicate) peel-off, pressure-sensitive, adhesive stickers be affixed in some way to the vials (primary packaging) of each vaccine for each dose contained therein. One sticker would be used for the patient's permanent paper medical record (if any, see UVAR form below). Another could be placed into a patient's take-home immunization "passport" booklet. A third could be applied to a form (not created by VISI) to be mailed to immunization registries.

5.2 The adhesive on these stickers should be designed for permanent adherence once placed on the medical record and a short grace period for repositioning expires. How these stickers might be affixed to the vials, and the nature of the adhesive and its performance characteristics are matters to be left by VISI to individual manufacturers and the FDA. Technology exists for the use of multiple peel-off labels superimposed one above another (as pioneered in Sweden for vaccine vials). Other stamp-dispenser type devices for attachment to multi-dose vials have also been invented, e.g.: <http://www.patents.ibm.com/details?pn=US05692640>.

5.3 Because of space limitations, VISI will specify that these peel-off stickers contain an RSS Limited Composite™ or an RSS-14 Stacked Composite™ "reduced space symbology" barcode containing the same numerical data as the full-size barcode for the secondary packaging. See: <http://www.aimglobal.org/standards/symbinfo/composite_overview.htm>, <http://www.uc-council.org/news/ne_p051998.html>, <http://www.ean-ucc.org/id_space_constrained_identific.htm>, <http://www.ean-ucc.org/id_healthcare.htm>.

5.4 The RSS™ standards remain in late draft status by UCC work groups and committees <http://www.ean-ucc.org/id_tech._groups.htm> determining whether the compressed 2-dimensional upper component of the barcode may be non-aligned with the conventional lower 1-dimensional component in order to permit "online printing" of lot number and expiration after the NDC data has been preprinted on a small label. Their final and formal promulgation will be incorporated by reference into the VISI.

5.5 It is expected that reading such miniaturized barcodes may require more sophisticated and expensive laser or imaging scanners that would be appropriate for immunization registries, but not necessary for physician's offices. Instead, computerized clinics with simpler scanners can scan the larger traditional barcode on the vaccine box.

5.6 In addition to the RSS barcode, each peel-off sticker (and any underlying label remaining on the vial) would contain in plain English text in a type size of at

least 6 points (or higher as mandated by FDA): (1) the representation in arabic numerals of the number string represented in the barcode (as required by UCC-EAN standards), (2) the boldfaced standardized abbreviation for the vaccine type (see below), (3) the standardized abbreviation for the vaccine manufacturer (see below), (4) the commercial brand name of the vaccine, (5) the NDC number, (6) the lot number (or the "pick" number for vaccines combined by the vaccinator from separate lots of different vaccines), and (7) the expiration date.

5.7 In addition, and space permitting, these peel-off and permanent labels of the vaccine vial may contain (1) the full official generic name of the vaccine, (2) the full name of the manufacturer and/or distributor, (3) logos or graphic embellishments, and any other information desired by the manufacturer and approved by the FDA.

5.8 A maximum size (width and height) for these peel-off labels will be specified by VISI based on compatibility with the Universal Vaccine Administration Record (UVAR) form (see below). However, no minimum size will be specified, and this issue shall be left up to the manufacturer and FDA.

5.9 TO BE DONE: (1) VISI must decide whether to recommend duplicate or triplicate stickers for each dose of vaccine (or leave triplicates to market forces), and whether a permanent label should remain on the vial after all peel-off stickers are removed. (2) VISI must set the minimum x-dimension of reduced size barcode for legibility, and the maximum width and height of a peel-off sticker. (3) Text must be drafted to adopt by reference the RSS composite™ barcoding and labelling standards. (4) The layout for the information on the stickers should be proposed. (5) New prototype samples of secondary-packaging barcodes and primary-packaging stickers illustrating these standards must be prepared for representative products from major manufacturers. (6) Funds must be identified for CDC to procure for VISI new printing software for barcode samples, and new laser and image scanning hardware to test them (~$1,200).

6. UNIFORM VACCINE ADMINISTRATION RECORD (UVAR) FORM

6.1 In medical practices that do not have barcode scanning systems to transfer vaccine identity into electronic patient records, a Uniform Vaccine Administration Record (UVAR) form is proposed by VISI:
<http://www.cdc.gov/nip/visi/prototypes/UVARform.pdf>
This form would accept either peel-off stickers from the vaccine vial, as well as pen or pencil entry of vaccine identifying information if stickers are lost or unavailable. The form could serve as the provider's permament, legal, medical record of the vaccination. Different forms might be developed to receive the triplicate peel-off stickers and be mailed to immunization registries (the design of such forms is not within the scope of VISI).

6.2 STATUS. (1) The UVAR form needs updating of manufacturer

names. (2) May need improved layout, style, and formatting.

7. UNIFORM VACCINE AND MANUFACTURER ABBREVIATIONS

7.1 Uniform, standard abbreviations for vaccine types and manufacturer abbreviations are proposed. One purpose is to minimize misinterpretation of ad hoc designations used in medical records, which may lead to erroneous conclusions as to the actual vaccine type and brand administered to a patient. Another advantage is to permit very small peel-off sticker labels to avoid the need for the full generic names of very large combination vaccines.

7.2 Draft prototypes of these two sets of abbreviations are available for working group review at:
<http://www.cdc.gov/nip/visi/prototypes/vaxabbrev.htm>
and
<http://www.cdc.gov/nip/visi/prototypes/mfgnames.htm>

7.3 STATUS: (1) Working group needs to consider dropping the discussion of "MVX codes" from the manufacturer abbreviation table, and/or the discussion and righthand columns of "HL7 codes" from the vaccine abbreviation table. These may be of interest only to a very limited audience involved in electronic communications among immunization registries. (2) The working group should consider the pros and cons of obtaining AMA permission to add to the vaccine abbreviation table a column of CPT codes for those vaccines assigned one.

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